EUROPEAN
COMMISSION

Brussels, 24.4.2015
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COMMISSION IMPLEMENTING DECISION

of 24.4.2015

relating to the designation of "Xenon" as an orphan medicinal product under Regulation (EC) No 141/2000 of the European Parliament and of the Council

(Text with EEA relevance)

(ONLY THE ENGLISH TEXT IS AUTHENTIC)

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THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products[1], and in particular the first sentence of Article 5(8) thereof,

Having regard to the application submitted by Neuroprotexeon Ltd on 9 December 2014 under Article 5(1) of Regulation (EC) No 141/2000,

Having regard to the favourable opinion of the European Medicines Agency, drawn up on 19 March 2015 by the Committee for Orphan Medicinal Products and received by the Commission on 26 March 2015,

Whereas:

(1) The application submitted by Neuroprotexeon Ltd concerning the medicinal product “Xenon” was validated on 19 January 2015 under Article 5(4) of Regulation (EC) No 141/2000.

(2) "Xenon" meets the designation criteria referred to in Article 3(1) of Regulation (EC) No 141/2000.

(3) The application should therefore be accepted,

HAS ADOPTED THIS DECISION:

Article 1

The medicinal product “Xenon” is designated as an orphan medicinal product for the indication: Treatment of perinatal asphyxia. It shall be entered in the Community Register of Orphan Medicinal Products under number EU/3/15/1483.

[1] OJ L 18, 22.1.2000, p.1.

Article 2

The European Medicines Agency shall make available to all interested parties the opinion of the Committee on Orphan Medicinal Products referred to in this Decision.

Article 3

This Decision is addressed to Neuroprotexeon Ltd, 52 Princes Gate, Exhibition Road, London SW7 2PG, United Kingdom.

Done at Brussels, 24.4.2015

For the Commission

Ladislav MIKO
Acting Director-General

CERTIFIED COPY
For the Secretary-General,

Jordi AYET PUIGARNAU
Director of the Registry
EUROPEAN COMMISSION